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14. ABSTRACT

Year 1 focused on pre-trial activities including the development of the experimental and control substance abuse interventions, corresponding counselor manuals, research protocols, recruitment advertisements and recruitment plan. IRB approvals from the University of Washington and HRPO for both phase 1 (pre-trial) and phase 2 (randomized controlled trial) research activities were obtained. In Year 2, the randomized controlled trial was initiated, counselors and research staff were hired and trained, and recruitment materials were finalized and implemented. Participant enrollment is on target and clinical sessions and follow-up assessments are underway.

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INTRODUCTION:

This study will develop and test a brief telephone-delivered motivational enhancement intervention (MET) for substance abusing military personnel who are not currently in substance abuse treatment. The intervention is designed to prompt: (a) a willingness to participate voluntarily in a self-appraisal of substance abuse behavior and consequences, (b) self-initiated change or enrollment in a treatment or self-help program, and (c) cessation of abuse of alcohol or other drugs. Following focus groups with 30 participants, this study will recruit 240 military personnel who have a current substance use disorder via local publicity. The recruitment period will extend over a period of 36 months. Following screening and a baseline assessment, enrolled participants will be randomly assigned to one of two study conditions, each consisting of one 30-60 minute session by phone: (1) the experimental MET condition, or (2) a brief educational session. The MET session will involve a counselor using motivational interviewing strategies to establish an empathic relationship, to support the caller in candidly exploring the problems he/she has experienced with alcohol/drugs, and weigh the pros and cons of future options. The educational session will be didactic and provide information on alcohol and drugs. Participants in both conditions will be reassessed at three and six months following exposure to the intervention. Participation in the trial will be over the duration of 7 months for each participant.

BODY:

The aims of the study are to: (1) manualize participant recruitment mechanisms (e.g., newspaper and radio advertisements, public service announcements, news releases, culturally-specific publicity mechanisms for events, flyers and brochures to be disseminated to human services agencies); (2) develop a motivational enhancement intervention for delivery by telephone to military personnel who are engaging in substance abuse and are not in treatment; (3) evaluate its efficacy in promoting treatment seeking and engagement, and (4) assess its impact on alcohol and drug use outcomes.

Study Team Formation: Year 1 included the initial steps of hiring and forming a collaborative study team. A system for meeting with study investigators on 3 occasions per month was established. Project goals and goals specific to Year 1 activities were outlined and progressively worked toward throughout the year. Roles and responsibilities of team members were established. Relationships were formed with our collaborators at Joint Base Lewis-McChord and meetings were held monthly. Collaborators at Joint Base Lewis-McChord actively advise and educate our team regarding services available to army personnel, the cultural competence of our study materials, recruitment processes, and assist with recruitment of focus group participants and obtaining meetings with key figures on post. A Project Coordinator was hired and trained. In August of 2010, our counselors and research assistants were hired and training began accordingly. Over Year 2, we experienced significant staff turnover. However, we were able to re-hire and train personnel in positions that were vacated so that Year 2 ended completely staffed. In August of 2011, a full-time Recruitment Coordinator was also hired.

Human Subjects Protection Review: In Year 1 the study team submitted human subjects protection applications for two phases of the research: pre-trial activities that included procedures for recruiting and conducting focus groups, and all activities associated with the controlled trial. Human subjects protection reviews were conducted by the University of Washington (UW) Institutional Review Board (IRB) and the U.S. Army Human Research Protection Office (HRPO). IRB and HRPO approvals were obtained prior to the initiation of pre-trial activities. Now, as the date approaches for beginning the controlled trial, an application was submitted to the UW IRB and approved on June 11, 2010. The approved application was then submitted to HRPO. Minor modifications were requested by HRPO and those were addressed and submitted to the UW IRB and HRPO and approved by UW and HRPO on September 15, 2010 and September 17, 2010, respectively. An application for a Certificate of Confidentiality (for the controlled trial) was submitted to the National Institute on Drug Abuse and approved

on August 21, 2010 and was granted. All investigators completed the required Collaborative Institutional Training Initiative IRB training course.

Manualize Participant Recruitment Mechanisms: In Year 1, print advertisements for the study were developed. These include advertisements to be placed in newspapers, pamphlets to be included in orientation packets for troops returning from deployment and for soldiers who are new to Joint Base Lewis-McChord, banners and posters to be placed on post, flyers for distribution to post locations (such as service agencies, health clinics, movie theaters, barracks, etc.), and advertisements on media screens throughout post. We have also collaborated with the Army Substance Abuse Program's prevention services to have our publicity materials included and introduced in alcohol and drug education classes. Several discussions with our colleagues at Joint Base Lewis-McChord have generated numerous employable ideas for recruitment with regard to on post advertisement placement.

In Year 2, additional print advertisements were developed that specifically targeted women, prescription drug abuse, and people of color. Other recruitment materials such as pamphlets and brochures were further refined. Print advertisements were placed throughout post. Locations included recreation centers; fitness centers and gyms; restaurants; community and training centers; medical, behavioral health and dental facilities; childcare centers; barracks; unit buildings; and social service agencies. Posters and brochures were also placed at a YMCA and restaurant off-post that have frequent active-duty patrons. Study advertisements were also published in two off-post newspapers that are distributed on and near Joint Base Lewis-McChord. Ads also ran on LCD screens throughout post and a large recruitment banner rotated between access gates. A webpage was created to provide more information to potential participants. Facebook ads were created and employed.

In addition to visual media, Year 2 also focused on in-person recruitment. Study staff have briefed service providers (unit representatives, chaplains and suicide prevention leaders) on the study so that they may refer soldiers. Staff also distributed recruitment

materials at two on-post events, a suicide prevention walk and an annual safety fair. Lastly, on-post collaborators are informing soldiers at reintegration briefings and demobilization briefings of the study.

Focus Groups: In Year 1, separate focus groups were conducted with 10 military personnel who use substances, 7 military personnel who have completed or are currently engaged in substance abuse treatment, and 9 Joint Base Lewis-McChord service providers. Focus group participants were recruited to provide feedback on recruitment advertisements and intervention materials and provided ideas for advertisement placement. Findings from the focus groups were analyzed and used to edit the recruitment materials and to form an advertisement plan.

Develop and Manualize MET Intervention for Target Population: In Year 1, counseling protocols were drafted for the MET and Education conditions. A personalized feedback report tailored to military personnel was developed. Feedback on the personalized feedback report was received and incorporated from the focus groups (described above) and our colleagues at Joint Base Lewis-McChord. Manuals for the Education and MET interventions were developed as well. A counselor training protocol was created. Counselors were hired and began training in August of 2010.

In Year 2, the Education condition was amended to include information about two new substances: Methylenedioxypyrovalerone (MDPV), commonly known as “bath salts”; and synthetic marijuana, commonly known as “Spice” or “K2.” Soldiers’ abuse of these substances has been a growing concern among Joint Base Lewis-McChord service providers and was therefore included in the intervention.

Conduct a Randomized Clinical Trial: Protocols for screening and assessment were developed in Year 1. Research assessment staff were hired and trained. InYear 2, Web-based follow-up assessments were created for participants who are unable to complete questionnaires by phone. Recruitment for the study began in late October 2010. To date, 223 individuals have called the study, 128 have completed the

screening for eligibility and 65 have enrolled. 41 participants have completed their clinical session, 27 completed the 3-month follow-up and 18 completed the final 6-month follow-up. As alluded to above, Year 2 included significant staff turnover which slowed the rate of recruitment for several months. Once staffing was resolved, recruitment caught up and our enrollment is now on target.

Clinical supervision with the counselor occurs weekly. Clinical sessions are listened to by the clinical director or PI and feedback is provided to avoid counselor drift. Research staff also meet weekly to discuss project progress and needs. Recordings of assessments are listened to regularly by supervisors and feedback is provided to maintain a high level of quality.

Other

We were invited to present our work to General Peter Chiarelli when he visited the University of Washington campus in May 2011. He appeared very interested in the study and was optimistic about its ability to reach and help Army personnel. At his request, we have been in discussions with ASAP personnel at Fort Campbell to see if the personnel and Command on that post are interested in having the study publicized there.

A talk entitled "*Overcoming barriers to reaching untreated army personnel with a substance use disorder: Concepts underlying a controlled trial of a motivational enhancement intervention ("Warrior Check-Up")*" was delivered at the annual conference for the Society for the Study of Social Problems in Las Vegas, Nevada in August of 2011. The talk was a part of a special session focusing on military populations and substance abuse.

KEY RESEARCH ACCOMPLISHMENTS:

- Pre-trial activities approved by UW and HRPO IRBs
- Focus groups completed

- Recruitment advertisements developed
- MET intervention developed
- Education intervention developed
- Main trial activities approved by UW and HRPO IRBs
- Certificate of Confidentiality obtained for main trial
- Efficacy Trial was initiated
- Participant recruitment and retention is on target

REPORTABLE OUTCOMES: N/A

CONCLUSION: The past year's activities have focused on initiating the efficacy trial and hiring and training staff. All study protocols were finalized, a web-based version of the follow-up assessments was created, and recruitment of participants is on target. The study is well positioned to meet its' targets within the time-frame proposed.

REFERENCES: N/A

APPENDICES: N/A

SUPPORTING DATA: N/A